SECTION II
REMARKS

Regarding the Claims

Claims 9, 10 and 16 have been amended as set forth in the above Complete Listing of the Claims. As amended, the claims are supported by the specification and the original claims. No new matter has been added, as defined by 35 U.S.C. § 132.

Specifically, claim 9 has been amended to delete the language "or the" mistakenly added in the preliminary amendment. Such amendment is made to return the claim to the form in which it was originally filed.

Claim 10 has been amended to add the modifier "the" prior to the term "microorganism" to properly reflect that the microorganism referred to is the microorganism of claim 6.

Claim 16 has been amended to add the language "or an antigen protein purified from said lactic acid bacterium," language which was originally present in the claims, as filed, and which was omitted in error from the listing of the claims presented with the preliminary amendment.

Thus, upon entry of the amendments, claims 1-19 will be pending, of which claims 3 and 5 are withdrawn. A Complete Listing of the Claims, as pending, is provided in Section I above.

Regarding the Restriction Requirement

The examiner has made the restriction requirement, as set forth in the Office Action of August 22, 2007 final. Applicant has elected the species of spike antigen protein in claims 1, 8, 9, and 15, SARS SC in claim 2, and lactic acid bacterium in claim 7. The examiner's withdrawal of the species election of a pgs complex is noted.

Rejection of Claims 1, 2, 4, 6-8, 14 and 15 Under 35 U.S.C. §103

Claims 1, 2, 4, 6-8, 14 and 15 are rejected under 35 U.S.C. § 103(a) as being obvious over Sung et al. (US 2005/0249752 A1) and Ho et al. (Biochemical and Biophysical Research Communications, 2004). Specifically, the examiner alleges that the *Lactobaccillus casei* bacteria expressing HPV antigens and pgs A, pgsB and/or pgsC inserted into a pHCE2LB vector

described in the cited Sung et al reference renders the claimed invention obvious. Applicants respectfully disagree.

35 U.S.C. §103(a) provides:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains...

The examiner has stated that "[b]ased upon the earlier effective U.S. filing date of the reference, it constitutes prior art, but only under 35 U.S.C. §102(e)." (Office Action mailed December 11, 2007, page 4.) The examiner also stated that "[a]pplicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 C.F.R. 1.55." Attached herewith, please find a certified translation of Korean Application No. 10-2003-0035993. By provision of such translation, priority of the present application is shown to the June 4, 2003 filing date of that application. It is respectfully submitted that the cited Sung et al. reference is not available as a prior art reference under 35 U.S.C. § 102(e) in view of the priority date of June 4, 2003 for the present application.

35 U.S.C. §102(e) provides:

> A person shall be entitled to a patent unless -
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> ...(e) the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language...

Sung et al. (US 2005/0249752 A1) was filed as a U.S. application on June 3, 2005 and published on November 10, 2005. The application claims priority to PCT/KR03/02163, filed October 17, 2003 in Korean and published April 29, 2004 in English, which, in turn, claims priority to Korean application 10-2002-0063378, filed October 17, 2002 and published April 28, 2004. For purposes of applicability of 35 U.S.C. §102, the date of first filing, June 4, 2003 is deemed to be

the date of invention of the present application. As the Sung et al. reference was filed in the PCT in Korean, designating the U.S. and was published in English, the relevant date of filing of the Sung et al. reference "in the United States" is the PCT filing date of October 17, 2003. As June 4, 2003 is prior to October 17, 2003, the date of the invention of the present application is prior to the date of first filing of the Sung et al. reference in the United States. Accordingly, the Sung et al. reference is not available as a prior art reference under 35 U.S.C. § 102(e) against the present application.

As the Sung et al. reference is not available as a prior art reference under 35 U.S.C. § 102(e) against the present application, the combination of Sung et al. and Ho et al. is not a valid basis for rejection of claims 1, 2, 4, 6-8, 14 and 15 of the present application under 35 U.S.C. § 103(a). Withdrawal of the rejection of claims 1, 2, 4, 6-8, 14 and 15 under 35 U.S.C. § 103(a) is therefore respectfully requested.

Rejection of Claims 9-13 and 16-19 Under 35 U.S.C. §112

Claims 9-13 and 16-19 are rejected under 35 U.S.C. §112, first paragraph as allegedly non-enabling. Applicants respectfully disagree.

In rejecting the claims, the examiner states that the specification is "enabling for producing antibodies in mice against recombinant *Lactobacillus casei* expressing SARS spike SA and SC and nucleocapsid NB antigens" but "does not reasonably provide enablement for a vaccine for SARS or preventing SARS through vaccine administration." (Office Action mailed December 11, 2007, page 6). The examiner then provides the *In re Wands* factors to support the position that claims 9-13 and 16-19 are not enabled.

In a discussion of "working examples" the examiner discusses the glycosylation of native SARS proteins, versus non-glycosylated antigens produced in the present invention. It is submitted that the lack of glycosylation on recombinant antigens when a native protein is glycosylated does not necessarily show that the recombinant proteins cannot be effective as antigens. In fact, numerous vaccines in the art utilize non-glycosylated proteins, where the native proteins are glycosylated. (See exemplary U.S. Patent Nos. 7,078,507, 5,747,526 and 4,462,333 and PCT application WO/2002/058725, discussed in detail below.) While these references describe viruses other than the SARS virus, they are effective to show that one of skill in the art would not assume that glycosylated and non-glycosylated proteins must have different anti-viral properties with regard

to any virus.

U.S. Patent No. 4,642,333 specifically describes vaccines "composed of one or more glycoproteins or their non-glycosylated amino acid chain..." that are effective against HSV 1 and 2.

In the Background section of U.S. Patent No. 5,747,526, HIV vaccines derived from gp120 are described and the inventors state that "[t]rial results show denatured non-glycosylated gp120 (ENV2-3) as well as conformationally intact, glycosylated gp120 are safe and immunogenic in HIV infected subjects."

Similarly, U.S. Patent No. 7,078,507 provides proteins useful in vaccines against malaria. In that specification, it is shown that

> "[T]he comparison of the properties of the N-glycosylated and non-N-glycosylated malaria proteins encoded by synthetic genes, especially their immunogenic properties resulted in the understanding that N-glycosylation of the EBP protein does not affect its properties important for its use in the anti-malaria vaccine compositions and vaccination methods."

PCT application WO/2002/058725 demonstrates that non-glycosylated proteins can be used in vaccines against RSV, despite the fact that glycosylated peptides are a large part of the native protein.

Vaccines containing non-glycosylated versions of native glycosylated proteins are well known in the art and are known to be immunologically effective. Accordingly, one of skill in the art would know that a non-glycosylated recombinant protein does not necessarily lack antigenic domain(s) and that such non-glycosylated recombinant proteins are able to provide an immunogenic response.

Accordingly, from the example set forth in the application, it is apparent that SARS spike SA, spike SC or nucleocapsid NB antigens can be recombinantly produced. Though the recombinant SARS spike SA, spike SC or nucleocapsid NB antigens may lack glycosylation, it is known in the art that recombinant non-glycosylated proteins can be effective anti-virals, even where the native proteins are glycosylated.

Accordingly, claims 9-13 and 16-19 are enabled by the present application, in compliance with the requirements of 35 U.S.C. § 112, first paragraph. Withdrawal of the rejection is therefore respectfully requested.